510(k) SUMMARY
Medtronic Sofamor Danek
MRI Update for T2 XVBR™ Spinal System &
T2 ALTITUDE™ Expandable Corpectomy Systems

SEP 2 3 2013

June 2013

I. **Company:**

Medtronic Sofamor Danek,
USA Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901)396-3133

II. **Contact:**

Becky Ronner
Regulatory Affairs Specialist
Telephone: (901)399-2757
Fax: (901)346-9738

III. **Proprietary Trade Name:**

T2 XVBR™ Spinal System
T2 ALTITUDE™ Expandable
Corpectomy System

IV. **Common & Classification Names:**

Spinal Intervertebral Body Fixation
Orthosis (21 CFR 888.3060)

Class:

Class II

Product Code:

MQP

V. **Description:**

T2 XVBR™ Spinal System

The T2 XVBR™ Spinal System is a distractible system. This construct is inserted between two vertebral bodies in the thoracic and/or lumbar spine and is expanded to aid in the surgical correction and stabilization of the spine. The construct is not intended to be used as a standalone device. The construct is intended to be used with either anterior and/or posterior supplemental spinal fixation systems already cleared for thoracic and lumbar spine stabilization.

The T2 XVBR™ expandable centerpiece is made of titanium alloy, cobalt chrome, and nitinol. The T2 XVBR™ Titanium Alloy end caps are attached to the T2 XVBR™ expandable centerpiece to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

The T2 XVBR™ Spinal System is available in multiple diameters and heights to accommodate the patient's anatomical requirements.

T2 XVBR™ Spinal System constructs may not be used with stainless steel supplemental fixation devices. One of the following Medtronic spinal systems or their successors must be used with the T2 XVBR™ Spinal System.

	Anterior	Posterior
ZPLATE-II™ Anterior Fixation System	x	
DYNA-LOK CLASSIC® Spinal System	x	x
VANTAGE® Anterior Fixation System	x	
TSRH® Spinal System	x	x
CD HORIZON® Spinal System	x	x

Do not use implant components from any other manufacturer with the T2 XVBR™ Spinal System. Stainless steel and titanium implants are not compatible with each other. They must not be used together in a construct. As with all orthopedic implants, in no case may the implants be re-used.

T2 ALTITUDE™ Expandable Corpectomy System

The T2 ALTITUDE™ Expandable Corpectomy System is a distractible system. This device is inserted between two vertebral bodies in the thoracic and lumbar spine and is expanded to aid in the surgical correction and stabilization of the spine. The device may be implanted through a lateral or posterior approach using a minimally invasive technique or implanted through a lateral, posterior or anterior approach through a traditional open technique. The device is not intended to be used as a stand-alone implant.

One of the following Medtronic Spinal System or their successors must be used with the T2 ALTITUDE™ Expandable Corpectomy System.

	Anterior	Posterior
VANTAGE® Anterior Fixation System	x	
TSRH® Spinal System	x	x
CD HORIZON® Spinal System	x	x

Do not use implant components from any other manufacturer with T2 ALTITUDE™ Expandable Corpectomy System components. Stainless steel and titanium implants are not compatible with each other. They must not be used together in a construct. As with all orthopedic implants, in no case may the implants be re-used.

The T2 ALTITUDE™ Expandable Corpectomy System is made of titanium alloy, cobalt chrome, and nitinol. The optional T2 ALTITUDE™ angled end caps may be attached to the T2 ALTITUDE™ expanding centerpiece to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

The T2 ALTITUDE™ Expandable Corpectomy System is available in multiple diameters and heights to accommodate the patient's anatomical requirements.

VI. Indications for Use:

T2 XVBR™ Spinal System

The T2™ Spinal System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The T2™ components consist of end caps which must be attached to a T2 XVBR™ expanding centerpiece to form a complete construct. The final construct is to be used with supplemental fixation. The T2 SCEPTOR™ components also serve as a vertebral body replacement device for the same intended use in the thoracolumbar spine. The T2 SCEPTOR™ end caps and endcleats must be attached to a PYRAMESH-C® device to form a complete construct. Both constructs (T2 XVBR™ and T2 SCEPTOR™) must be used with supplemental fixation to form a final construct. Specifically, the construct is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNA-LOK CLASSIC® Spinal System, the VANTAGE™ Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, or their successors. Additionally, the T2™ Spinal System construct is intended to be used with allograft and/or autograft.

T2 ALTITUDE™ Expandable Corpectomy System

The T2 ALTITUDE™ Expandable Corpectomy System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The T2 ALTITUDE™ Expandable Centerpiece may be used with or without optional modular endcaps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation. Specifically, the construct is to be used with the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, or their successors. Additionally, the T2 ALTITUDE™ Expandable Corpectomy System is intended to be used with allograft and/or autograft.

VII. Summary of Technological Characteristics:

The purpose of this bundled 510(k) application is to provide appropriate MRI safety labeling for the subject devices, while also providing MRI technologist with a method of concluding whether an MRI scan can be performed on the device and specific instructions on how to perform the scan. The systems in this 510(k) submission have been determined to be MR conditional per ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

The design/specifications of the subject devices are not being addressed. No changes have occurred for the devices in the subject product families, which are considered substantially equivalent to and previously cleared under previous 510(k) submissions such as:

- T2 XVBR™ Spinal System
  K091883 (S.E. 09/21/2009)
- T2 ALTITUDE™ Expandable Corpectomy System
  K100976 (S.E. 10/21/2010)

VIII. Discussion of Non-Clinical Testing:

In accordance with FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" testing has been completed. The following standards were followed to provide a determination that the subject devices in this 510(k) submission are MR Conditional in 1.5 Tesla and 3.0 Tesla MR environment:

- ASTMF2052 – "Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment"
- ASTM F2182 – "Standard test method for measurement of radio frequency induced heating on or near passive implant during magnetic resonance imaging."
- ASTM F2213 – "Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment."
- ASTM F2119 – "Standard test method for evaluation of MR image artifacts from passive implants."
- ASTM F2503 – "Standard practice for marking medical devices and other items for safety in the magnetic resonance environment"

IX. Conclusion:

Non-clinical testing in accordance with the standards listed above was completed along with a risk analysis. Based on the test results and additional supporting documentation provided within this pre-market notification, Medtronic believes that the subject devices demonstrate substantial equivalence to the listed predicate devices and should be labeled as MR Conditional in accordance with ASTM F2503 – "Standard practice for marking medical devices and other items for safety in the magnetic resonance environment".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 23, 2013

Medtronic Sofamor Danek USA, Incorporated
Ms. Becky Ronner
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K131888
Trade/Device Name: T2 XVBR™ Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: June 24, 2013
Received: June 25, 2013

Dear Ms. Ronner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K131888

Device Name: T2 XVBR™ Spinal System

Indications for Use:

The T2™ Spinal System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The T2™ components consist of end caps which must be attached to a T2 XVBR™ expanding centerpiece to form a complete construct. The final construct is to be used with supplemental fixation. The T2 SCEPTOR™ components also serve as a vertebral body replacement device for the same intended use in the thoracolumbar spine. The T2 SCEPTOR™ end caps and endcleats must be attached to a PYRAMESH-C® device to form a complete construct. Both constructs (T2 XVBR™ and T2 SCEPTOR™) must be used with supplemental fixation to form a final construct. Specifically, the construct is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNA-LOK CLASSIC® Spinal System, the VANTAGE™ Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, or their successors. Additionally, the T2™ Spinal System construct is intended to be used with allograft and/or autograft.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

510(k) Number (if known): K131888

Device Name: T2 ALTITUDE® Expandable Corpectomy System

Indications for Use:

The T2 ALTITUDE™ Expandable Corpectomy System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The T2 ALTITUDE™ Expandable Centerpiece may be used with or without optional modular endcaps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation. Specifically, the construct is to be used with the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, or their successors. Additionally, the T2 ALTITUDE™ Expandable Corpectomy System is intended to be used with allograft and/or autograft.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices